IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

ANNETTE SUTPHIN,

Plaintiff,

v. CIVIL ACTION NO. 2:14-cv-01379

ETHICON, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER

Pending before the court are numerous Motions *in Limine* filed by Plaintiff Anne Sutphin [ECF Nos. 48, 128, 130, 224, 227, 263, 264, 265] and Defendant Ethicon, Inc. ("Ethicon") [ECF Nos. 71, 208, 210, 212, 214, 216, 218, 279, 320]. The parties have responded and either replied or allowed the time for replies to expire, and the Motions are now ripe for consideration. For the reasons that follow, ECF Nos. 48, 208, and 216 are **GRANTED** and ECF Nos. 128, 130, 210, 212, 214, 218, 224, 227, 263, 264, 265, and 320 are **DENIED**. ECF Nos. 71 and 279 are **GRANTED in part** and **DENIED in part**. Many of the denied Motions were unopposed and have been **DENIED AS MOOT.** The parties are expected to abide by their concessions in response to each Motion.

I. Plaintiff's Motions *in Limine*

A. ECF No. 48 – Motion to Exclude FDA 510(k) Evidence

Matt Thiesson says on an album cover that: "The only thing worse than beating a dead horse is betting on one." Here, defense counsel bets again on a horse long interred. I assume that this is because, as Thiesson sings: "Opinions are immunity to being told you're wrong." I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, *see e.g., In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2020 WL 774239, at *4 (S.D.W. Va. Feb. 13, 2020), and I will continue to do so in this case, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See id.* at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."); *see also Rodriguez v. Stryker Corp.*, 680 F.3d 568, 574 (6th Cir. 2012) ("The 510(k) process does not comment on safety."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *In re C. R. Bard, Inc.*, 81 F.3d at 922. Accordingly, evidence or expert testimony related to the section 510(k) clearance of Defendant's mesh products, including the TVT-O, or the lack of FDA enforcement

action relative to Defendant's products, is **EXCLUDED**. Insofar as this Motion challenges the FDA-related testimony of the 510(k) clearance process, the FDA involvement in the TVT-O product, and the lack of FDA enforcement actions, I **GRANT** the Motion [ECF. No. 48].

B. ECF No. 128 – Motion to Preclude any Evidence or Argument Related to the April 14, 2018 *New York Times* [Article] and/or that Plaintiff's Expert has Interfered in her Medical Treatment

Plaintiff's Motion *in Limine* seeks to exclude certain evidence or argument suggesting that Plaintiff's expert, Dr. Margolis, interfered in Plaintiff's medical treatment. Plaintiff has identified two sources of such evidence. First, Plaintiff asks this Court to exclude an April 14, 2018, *New York Times* article entitled "How Profiteers Lure Women Into Often Unneeded Surgeries" ("the *New York Times* article"), which documents a scheme among plaintiffs' attorneys, doctors, and litigation finance companies to persuade women with pelvic mesh implants to undergo unnecessary medical procedures to make their lawsuits against manufacturers like Ethicon more lucrative. Next, Plaintiff asks the Court to exclude evidence that Dr. Margolis proactively contacted Plaintiff's treating physician, Dr. Stephen Bush, to discuss Plaintiff's treatment. Plaintiff asserts that this evidence is irrelevant and prejudicial.

Ethicon has stated that it does not intend to introduce the *New York Times* article at trial for the purpose of showing that Plaintiff was induced by her attorney or some other improper source to undergo revision surgery. However, in the event that Plaintiff attempts to reference the number of women who have filed suit against

pelvic mesh manufacturers like Ethicon or who have undergone surgery to remove pelvic mesh products, Ethicon argues that it should then be able to present the *New York Times* article to provide context for the numerous factors driving decisions to take out pelvic mesh products. Accordingly, I lack the context needed to make a substantive ruling on this matter and therefore **DENY without prejudice** the Motion [ECF No. 128] as it relates to the *New York Times* article.

As far as the evidence that Dr. Margolis proactively contacted Plaintiff's treating physician, Dr. Stephen Bush, to discuss Plaintiff's treatment, I **DENY** Plaintiff's Motion [ECF No. 128]. This evidence goes to the credibility and veracity of statements made by Dr. Margolis.

C. ECF No. 130 – Motion to Preclude any Evidence or Argument Pertaining to Plaintiff's Unrelated Medical Conditions

Plaintiff moves to preclude any evidence or argument pertaining to her prior unrelated medical conditions and procedures. Ethicon asserts that it does not intend to introduce evidence of the following six conditions: polycythemia vera, osteoporosis, sleep apnea, bilateral tubal ligation, colonic polyps, and allergic rhinitis. Ethicon does intend to introduce evidence of the following two conditions: (1) orthopedic neck pain/cervical radiculopathy, and (2) osteoarthritis.

As I have previously held, "evidence about preexisting injuries, including neck and back pain, can conceivably serve various roles in Ethicon's case, such as demonstrating [Plaintiff's] pre-implant quality of life and pain management; breaking the chain of proximate causation; and establishing damages, or the lack thereof, existing in this case." *Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, 2014 WL

6680356, at *9 (S.D.W. Va. Nov. 25, 2014) ("While the plaintiff argues that these preexisting medical conditions are 'wholly unrelated' to the plaintiff's claims…the province of weighing the testimony and determining the relationship, if any, among [Plaintiff's] injuries belongs to the jury."). Accordingly, I **DENY** the Motion [ECF No. 130] as to the following two conditions: (1) orthopedic neck pain/cervical radiculopathy, and (2) osteoarthritis, and **DENY AS MOOT** the Motion as it relates to the six conditions Ethicon does not intend to introduce.

D. ECF No. 224 – Motion to Preclude Argument or Commentary Regarding Mesh Litigation As "Lawyer-Driven" and Attorney Advertising Practices

Plaintiff first moves to exclude any argument or commentary that pelvic mesh litigation is "lawyer-driven." Ethicon asserts that it does not intent to make this argument at trial. Accordingly, with respect to this statement, I **DENY AS MOOT** the Motion [ECF No. 224].

Plaintiff also moves to exclude any argument or commentary related to advertising by Plaintiff's attorneys seeking to represent women in this litigation. Ethicon responds that the court should not exclude evidence or statements regarding the specific advertisement that prompted Plaintiff to file this lawsuit as it is relevant to her credibility. I have previously held that statements related to whether a plaintiff saw an attorney advertisement prior to filing suit are "probative of her credibility regarding her injuries." *Lewis v. Ethicon*, Nos. 2:12–MD–02327, 2:12–cv–4301, 2014 WL 505234, at *3 (S.D.W. Va. Feb. 5, 2014). Accordingly, I **DENY** the Motion [ECF No. 224] with regard to attorney advertising.

E. ECF No. 227 – Motion to Preclude any Reference to Johnson & Johnson or its Subsidiaries' Efforts to Create a Vaccine for or Otherwise Combat COVID-19.

Ethicon asserts that it does not intend to offer any argument or evidence relating to Johnson & Johnson's or any other entity's efforts to develop a vaccine for or otherwise combat COVID-19. Accordingly, I **DENY** the Motion [ECF No. 227] **AS MOOT**.

F. ECF No. 263 – Motion to Preclude any Reference to the AUGS/SUFU Position Statement

I have repeatedly denied similar motions to exclude the AUGS/SUFU Position Statement because it may be relevant and admissible for multiple reasons. *See e.g. Lewis v. Ethicon, Inc.*, 2014 WL 505234, at*2 (S.D.W. Va. Feb. 5, 2014); *Huskey v. Ethicon, Inc.*, 2014 WL 3861778, at *2 (S.D.W. Va. Aug. 6, 2014); *Edwards v. Ethicon, Inc.*, 2014 WL 3882186, at *3 (S.D.W. Va. Aug. 7, 2014); *Tyree v. Boston Scientific Corp.*, 2014 WL 5445769, at *14 (S.D.W. Va. Oct. 22, 2014); *Fowler v. Boston Scientific Corp.*, 2016 WL 2983696, at *4 (S.D.W. Va. May 20, 2016). As I have previously explained,

> First, to the extent that the Position Statement is relied upon by an expert witness, it may be admissible under the learned treatise exception to the hearsay rule. Second under Rule 703, experts are permitted to rely on otherwise inadmissible information provided that they "would reasonably rely on those kinds of facts or data in forming an opinion on the subject." Third, [the defendant's] state of mind is relevant to the punitive damages claim, and "[a]n out-of-court statement that is offered to show its effect on the hearer's state of mind is not hearsay under Rule 801(c)."

Huskey, No. 2:12-cv-5201, 2014 WL 3861778, at *2 (S.D.W. Va. Aug. 6, 2014)

(citations omitted) (second alteration in original) (quoting Fed. R. Evid. 703; *United States v. Thompson*, 279 F.3d 1043, 1047 (D.C. Cir. 2002)). For these same reasons, I **DENY** this Motion [ECF No. 263].

G. ECF No. 264 – Motion to Preclude Evidence or Argument that the TVT-O is the "Standard of Care" for SUI

I have previously denied similar motions concerning whether TVT was the "gold standard" or "standard of care" for treating SUI. *See e.g.*, *Lewis v. Ethicon, Inc.*, 2014 WL 505234, at*3 (S.D.W. Va. Feb. 5, 2014). I adopt the same reasoning here. Whether TVT-O is the "standard of care" is highly probative: "it goes to the very essence of whether the TVT is unreasonably dangerous or whether there exists a safer alternative design." *Id.* Further, I find that the term "standard of care" will not confuse the jury. To the extent Plaintiff believes the term is confusing in this case, she may cross-examine the witnesses on that point. Accordingly, I **DENY** the Motion [ECF No. 264].

H. ECF No. 265 – Motion to Preclude Duplicative and/or Cumulative Testimony from Defendants' Experts

In essence, this Motion seeks to reaffirm Federal Rule of Evidence 403 which prohibits the introduction of needlessly cumulative evidence where the probative value is substantially outweighed. The parties do not need the court to rule on or restate the obvious. To the extent Plaintiff believes trial testimony becomes needlessly cumulative, she is free to object at trial. Accordingly, I **DENY** this Motion [ECF No. 265] **without prejudice.**

II. Ethicon's Motions *in Limine*

A. ECF No. 71 – Ethicon's Omnibus Motion

In an effort to consolidate its Motions *in Limine*, Ethicon filed an Omnibus Motion seeking to exclude twenty separate pieces of evidence. I address each portion of Ethicon's Motion individually below.

1. TO PRECLUDE ANY ARGUMENT OR EVIDENCE REGARDING SPOLIATION

Plaintiff does not intend to present evidence regarding spoliation of evidence. Accordingly, this motion is **DENIED AS MOOT**.

2. TO PRECLUDE THE MAGNIFIED, GRAPHIC IMAGES ATTACHED TO THE SUPPLEMENTAL REPORT OF DR. MARGOLIS, PLAINTIFF'S CASE-SPECIFIC EXPERT

Ethicon moves to exclude the magnified images of Plaintiff's vulvar abscesses and infection of the right labia, which were attached to the supplemental expert report of Plaintiff's case-specific expert, Dr. Margolis, and which Plaintiff has identified as a trial exhibit. *See* Exh. 4: Mar. 30, 2018, Supp. Rep., "Sutphin Photographs Taken by Michael T. Margolis, MD, on 3/2718"); Pl. Exh. List, Doc. 51, PageID #819, Exh. 47 ("Rule 26 Expert Report of Michael Thomas Margolis, MD"); PageID #1038, Exh. 6003 (identifying both initial and supplemental reports). Ethicon moves to exclude these images under Rules 401, 402, and 403 of the Federal Rules of Evidence. Specifically, Ethicon argues that the images are irrelevant under Rule 401 because they do not make a consequential fact more or less probable than it would be without the images. Ethicon does not dispute that Plaintiff had the vulvar abscess depicted in the images. Instead, the question for the jury is whether the TVT-O device caused the abscess. Ethicon asserts that the images do nothing to make liability more

or less probable because they do nothing other than show the existence of the abscess and there is no visible mesh in the images. Further, to the extent I find that the images have any probative value, Ethicon argues they are still inadmissible under Rule 403 because the probative value is substantially outweighed by the danger of unfair prejudice. That is, Ethicon argues the graphic images serve no purpose other than to shock and inflame the jury.

Plaintiff argues the images are relevant because Dr. Margolis will use them to support his testimony and make it more probable that the TVT-O caused the abscess. Plaintiff further argues the images are necessary to show the location of the abscess and its appearance at the time of Dr. Margolis' examination, and to show the relevant anatomical structures. However, recognizing the sensitive nature of the images, Plaintiff states that she does not intend to display them on any screens during trial. Instead, Plaintiff argues she should be permitted to move the images into evidence, place them in a folder, and give them to the jury to review at each juror's individual discretion. In its Reply, Ethicon argues Plaintiff's proposed method of showing the images to the juror is more inflammatory than simply projecting them on a screen in the courtroom for the jury to view simultaneously. Ethicon further argues that, in any event, other diagrams and animations that are less graphic can be used to explain the location of the abscess and the relevant anatomical structures.

I have previously denied a motion *in limine* by Ethicon concerning Photographic or Video Depiction of Actual Prolift Surgery. *See Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, 2014 WL 6680356, at *1 (S.D.W. Va. Nov. 25, 2014) ("[T]he

following motions are **DENIED**…Ethicon's Omnibus Motion *in Limine* No. 5 Concerning Photographic or Video Depiction of Actual Prolift Surgery [Docket 206].”). Similarly, I **DENY** Ethicon's Motion here.

3. **TO PRECLUDE EVIDENCE OF COMPLICATIONS NOT ALLEGED BY MS. SUTPHIN**

Ethicon moves to exclude any evidence or argument that the TVT-O can cause adverse reactions or events other than those alleged by Plaintiff.

I have previously held that, under West Virginia law, “evidence of complications that no plaintiff experienced is irrelevant and lacking in probative value. For the claims that require evidence of injury (strict liability for failure to warn, strict liability for design defect, and negligence), only the injuries experienced by the complainant are relevant.” *Tyree v. Boston Scientific Corp.*, 2014 WL 5445769, at *6 (S.D.W. Va. Oct. 22, 2014). Therefore, I **GRANT** this Motion.

4. **TO PRECLUDE EVIDENCE OF PAYMENTS TO MEDICAL SOCIETIES**

Ethicon argues that evidence of payments to medical societies should be excluded. To the extent that Ethicon's motion concerns deposition testimony of Martina Scheich, Plaintiff agrees that she will not play Ms. Scheich's deposition testimony at trial unless her deposition has been completed before then. In this regard, I **DENY** the Motion **AS MOOT**.

However, to the extent that Plaintiff wishes to present evidence of payments to medical societies and/or the connections between Ethicon and the physicians who are responsible for certain position statements, or between Ethicon and the authors of favorable studies, the Motion is **DENIED**. *See Lewis v. Ethicon, Inc.*, No. 2:12-CV-

4301, 2014 WL 505234, at *6–7; *10 (S.D.W. Va. Feb. 5, 2014) ("[E]vidence about [a witness's] financial interest is probative of the negligence and punitive damages claim and is not unduly prejudicial.").

5. TO PRECLUDE INCOURT DEMONSTRATIONS OR TESTING OF EXEMPLAR DEVICES

Next, Ethicon argues that Plaintiff should be precluded from introducing into evidence any mesh exemplar devices, performing in-court demonstrations or testing. I will allow the exemplar device to be used as a demonstrative aid in court, so I **DENY** the motion as to this point. However, as I previously held in *Huskey v. Ethicon*, et al., Civ. A. No. 2:12-cv-05201 (S.D.W. Va. Sept. 4, 2014), jurors will not be permitted to physically examine the devices, and the devices will not go back into the jury room.

6. TO PRECLUDE REFERENCE TO "CONFIDENTIALITY" STAMPS ON PRODUCED DOCUMENTS OR REFERENCE TO ANY DOCUMENT NOT PUBLICLY DISSEMINATED AS "SECRET" INTERNAL DOCUMENTS

Ethicon moves to exclude any reference to company documents as "secret" or "confidential." Specifically, Ethicon requests that I prohibit Plaintiff not only from referring to "confidential" stamps on documents but also from offering evidence or argument that Ethicon's corporate documents were held in confidence before discovery began. Plaintiff argues that she will not refer to the designation of documents as confidential. While Plaintiff agrees not to mention that a document or piece of information was marked "confidential" or kept "secret" or "hidden" in connection with discovery, Plaintiff argues she should be permitted to inform the jury that evidence and information, known to Ethicon, was not provided to the medical community, Plaintiff, or her physicians.

Time after time, this court has ruled that whether a document is designated as confidential is entirely irrelevant. *See e.g., Carroll v. Bos. Sci. Corp.*, No. 2:13-CV-11601, 2016 WL 3031063, at *3 (S.D.W. Va. May 24, 2016). The court will, as always, instruct the jury to disregard the confidentiality markings on documents presented at trial. I **GRANT** Ethicon's Motion on this point.

7. TO PRECLUDE EVIDENCE OF POST-IMPLANT REVISIONS TO THE TVT-O IFU AND PATIENT BROCHURE

Ethicon anticipates that Plaintiff will seek to admit evidence regarding the 2015 revisions to the TVT-O IFU. Ethicon argues that any revisions made after Plaintiff's February 24, 2009, implant surgery should be excluded because they are inadmissible subsequent remedial measures (Fed. R. Evid. 407), are irrelevant (Fed. R. Evid. 401, 402), and even if relevant, would confuse the issues and mislead the jury (Fed. R. Evid. 403).

Evidence of subsequent remedial measures is inadmissible to prove "negligence; culpable conduct; a defect in a product or its design; or a need for warning or instruction." Fed. R. Evid. 407. However, the evidence may be admitted "for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures." *Id.* In other words, the admissibility of such evidence depends on the context and method by which Plaintiff seeks to introduce it. Accordingly, I **GRANT** Defendant's Motion as to allowing evidence of subsequent remedial measures to prove "negligence; culpable conduct; a defect in a product or its design; or a need for warning or instruction." *See Werner v. Upjohn Co.*, 628 F.2d 848, 859 (4th Cir. 1980) ("If subsequent warnings are admitted to prove

antecedent negligence simply because FDA required or might have required the change, then drug companies may be discouraged from taking early action on their own and from participating fully in voluntary compliance procedures."); *see also Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 541933, at *7 (S.D.W. Va. Feb. 10, 2015). To the extent Plaintiff attempts to introduce this evidence for another purpose at trial, Ethicon may object where appropriate.

8. TO PRECLUDE EVIDENCE THAT ETHICON DOES NOT CONTINUE TO SELL CERTAIN DEVICES

Plaintiff states that she does not intend to present evidence regarding the products Ethicon took off the market. Plaintiff asserts, however, that depending on Ethicon's presentation of evidence, such evidence and testimony may become relevant. At this time, I **DENY AS MOOT** the Motion. Should Plaintiff attempt to admit such evidence at trial, Ethicon may reassert its Motion.

9. TO PRECLUDE EVIDENCE OF THE WITHDRAWAL OF THE BOSTON SCIENTIFIC PROTEGEN DEVICE

Plaintiff does not intend to present evidence regarding the withdrawal of the Boston Scientific Protegen device. Accordingly, I **DENY AS MOOT** this Motion.

10. TO PRECLUDE EVIDENCE OF OTHER LAWSUITS AGAINST ETHICON, INCLUDING THOSE CONCERNING ETHICON'S OTHER PRODUCTS

Ethicon argues that evidence of other lawsuits or claims against Ethicon, including those concerning Ethicon's other products, is irrelevant to the issues here, is unreliable hearsay, and serves no purpose other than improperly impugning Ethicon's character. Further, if admitted, fairness would compel that Ethicon be allowed to rebut it, and that would waste trial time on collateral matters.

Evidence of other lawsuits and the factual allegations therein is inadmissible under Rule 403. *See Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 505234, at *6 (S.D.W. Va. Feb. 5, 2014). Although other lawsuits may ultimately show that the TVT-O is defective, the jury must still find that the TVT-O caused Plaintiff's injuries. Evidence of other lawsuits is likely to confuse and mislead the jury from that task, and it is highly prejudicial to Ethicon. Accordingly, I **GRANT** Ethicon's Motion on this issue.

11. **TO PRECLUDE EVIDENCE CONCERNING ANY MATERIAL SAFETY DATA SHEETS, INCLUDING ANY SUGGESTION THAT POLYPROPYLENE CAUSES OR MAY CAUSE CANCER**

Plaintiff asserts that she does not intend to introduce any Material Safety Data Sheets ("MSDS") for any product other than the one used in the TVT-O. The MSDS that relates to the TVT-O here is the Sunoco MSDS for C4001 Polypropylene Homopolymer (4/13/05) (the "Sunoco MSDS"), attached as Exh. 37; *see* Pl. Exh. List, Doc. 51, PageID #859 (identifying Exh. 1141). Accordingly, to the extent Ethicon seeks to exclude any MSDS other than the Sunoco MSDS, I **DENY** the Motion **AS MOOT**.

As to the Sunoco MSDS, this MSDS applies to raw polypropylene, which is an ingredient, but not to the finished product, used to make Ethicon mesh. Ethicon argues that the Sunoco MSDS, and any testimony based on it, including any suggestion that polypropylene causes or may cause cancer, should be excluded. Ethicon argues that Plaintiff wants to introduce the Sunoco MSDS specifically because it suggests the raw polypropylene may lead to an increased risk of cancer.

And, as Ethicon points out, I have excluded this same MSDS in another case where the plaintiff did not have or allege any injuries related to cancer. *See Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 505234, at *10 (S.D.W. Va. Feb. 5, 2014). Because Plaintiff here also does not have or allege any injuries related to cancer, I also **GRANT** this Motion **in part** and **EXCLUDE** the Sunoco MSDS to the extent that it relates to an increased risk of cancer.

However, Plaintiff asserts that she has other legitimate reasons to introduce the Sunoco MSDS. Specifically, Plaintiff points to a warning contained in the MSDS that the polypropylene was subject to degradation due to oxidizing agents known to be present in the human body. To the extent Plaintiff seeks to introduce the MSDS as evidence that Ethicon had notice of this warning, she argues it is not hearsay and is admissible for a purpose other than the truth. I have previously allowed discussion of a different MSDS to the extent it was offered to show "that the statements within it were made or that they had some effect on the future actions of a listener, or for the more limited purpose of providing relevant context or background." *In re C. R. Bard, Inc., Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2187, 2013 WL 3282326 at *3 (S.D.W. Va. June 27, 2017) (internal quotation marks omitted). The Fourth Circuit affirmed. *See In re C.R. Bard, Inc., MDL No. 2187, Pelvic Repair Sys. Prods. Liab. Litig.*, 810 F.3d 913, 926 (4th Cir. 2016) (holding that the MSDS at issue was admissible to "prove something other than its truth . . . includ[ing] statements used to charge a party with knowledge of certain information.").

Accordingly, to the extent Plaintiff seeks to introduce the Sunoco MSDS for a

purpose other than its truth, I **DENY** the Motion **in part.**

12. TO PRECLUDE THE DVD CONCERNING KUGEL COMPOSIX HERNIA MESH

Plaintiff does not intend to play the 2007 video featuring Dr. Todd Heniford entitled, "The Benefits of Lightweight Meshes in Ventral Hernia Repair." Accordingly, I **DENY AS MOOT** this Motion.

13. TO PRECLUDE THE USE OF DEPOSITION VIDEOS OR TESTIMONY, OR ANY VIDEO, IN OPENING

Plaintiff states that she does not intend to use video clips during opening statements. Plaintiff also states that she does not oppose this portion of the Motion, if the ruling applies to Ethicon as well. I **GRANT** the Motion. Both Ethicon and Plaintiff are precluded from the use of deposition videos in openings.

14. TO PRECLUDE BRIAN LUSCOMBE'S INTERNAL MARKETING PRESENTATION, THE "TOP TEN REASON [SIC] TO PURSUE . . . GYNECARE TVT OBTURATOR SYSTEM"

Given the Court's rulings in *Huskey* and *Lewis* on this issue, Plaintiff states that she will not seek to present evidence of the "Top Ten" PowerPoint. Accordingly, I **DENY** this Motion **AS MOOT**.

15. TO PRECLUDE EVIDENCE OR ARGUMENT ABOUT UNRELATED INVESTIGATIONS OR RECALLS OF OTHER JOHNSON & JOHNSON OR ETHICON PRODUCTS

Plaintiff does not intend to present evidence about investigations and/or government action related to Topamax, Motrin, Risperdal, Doribax or Tylenol, as well as product recalls concerning potential contamination during manufacturing of these products. Accordingly, I **DENY** this Motion **AS MOOT**.

16. TO PRECLUDE EVIDENCE OR ARGUMENT RELATING TO MEDICAL DEVICE REPORTS, REPORTS OF ADVERSE EVENTS FURNISHED BY PHYSICIANS, SUMMARIES OF THOSE REPORTS, AND/OR AGGREGATE NUMBERS OF MDRS FOR TVT-O OR ANY OTHER PRODUCT

As I have previously stated, an evidentiary ruling on whether to preclude Medical Device Reports "depends on the particular content of the evidence and argument, and the context in which the party seeks to introduce it. I simply cannot make a substantive ruling at this time without additional information. Therefore, a blanket exclusion of such evidence, argument, or testimony would be premature." *Watkins v. Cook Inc.*, No. 2:13-CV-20370, 2015 WL 1395638, at *5 (S.D.W. Va. Mar. 25, 2015). Accordingly, I **DENY** the Motion **without prejudice** at this time.

17. TO PRECLUDE EVIDENCE OR ARGUMENT RELATING TO ANECDOTAL CASE REPORTS OR CASE SERIES OR ARTICLES OR TREATISES BASED ON THEM

Ethicon argues that at trial, Plaintiff may seek to introduce certain anecdotal case reports or case series or expert testimony based on the reports to argue that TVT-O mesh surgery frequently has harmful outcomes. Ethicon argues these reports should be excluded.

Consistent with my rulings on similar motions *in limine* in prior cases, I **DENY** Ethicon's motion because I lack the context needed to make a substantive ruling on this matter at this time. *See e.g., Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, 2014 WL 6680356, at *4 (S.D.W. Va. Nov. 25, 2014); *Eghnayem, et al. v. Boston Scientific Corp.,* No. 2:13–cv–07965, 2014 WL 5465741, at *13 (S.D.W. Va. Oct. 28, 2014); *see also Lewis, et al. v. Ethicon, Inc.,* No. 2:12–cv–4301, 2014 WL 505234, at *5 (S.D.W. Va. Feb. 5, 2014).

18. TO PRECLUDE EVIDENCE OF PAYMENTS UNDER THE 1997 LICENSE AND SUPPLY AGREEMENT BETWEEN MEDSCAND AND JOHNSON & JOHNSON INTERNATIONAL

Ethicon moves to exclude any reference to or admission of evidence concerning any "milestone payments" made under a 1997 License and Supply Agreement between Medscand and Johnson & Johnson International. Ethicon argues that in the face of overwhelming evidence that Dr. Ulmsten did not bias his testing or act unethically, there should be no room for speculation about bias in an original study 20 years ago.

I have previously ruled on whether evidence that Professor Ulf Ivar Ulmsten, the inventor of the TVT, received "milestone payments" during the development of the TVT should be admitted. *See Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 505234, at *6–7 (S.D.W. Va. Feb. 5, 2014). In that case, I stated that "evidence about Professor Ulmsten's financial interest is probative of the negligence and punitive damages claim and is not unduly prejudicial." *Id.* My ruling here is consistent with previous rulings. Accordingly, I **DENY** the motion.

19. TO PRECLUDE EVIDENCE AND ARGUMENT RELATING TO A JULY 2003 EMAIL EXCHANGE BETWEEN TERRY COURTNEY AND DR. MARTIN WEISBERG

Given the Court's rulings in *Lewis* on this issue, Plaintiff will not seek to present Dr. Weisberg's email referring to the "wire brush thing." Plaintiff notes that she does oppose the Motion to the extent Ethicon seeks to preclude emails beyond Dr. Weisberg's email referring to the "wire brush thing." This portion of Ethicon's Motion does not address further emails. Accordingly, I **DENY** the Motion **AS MOOT**.

20. TO PRECLUDE EVIDENCE AND ARGUMENT RELATING TO THE EMAIL STRING BETWEEN AXEL ARNAUD AND MARTIN WEISBERG REGARDING PROLENE SOFT MESH

Given the Court's ruling in *Huskey*, Plaintiff does not intend to present evidence relating to Axel Arnaud and Martin Weisberg's email string discussing Prolene soft mesh. Accordingly, I **DENY** the Motion **AS MOOT**.

B. ECF No. 208 – Motion to Preclude Evidence or Argument Concerning Lawsuits filed by Patients of Defense Experts

Ethicon anticipates that Plaintiff may attempt to introduce or otherwise rely upon evidence regarding pelvic mesh lawsuits that have been filed by patients of Ethicon's experts. Such lawsuits would not be limited to the TVT-O device at issue in this case; in fact, Ethicon anticipates that Plaintiff will attempt to introduce evidence of lawsuits filed by patients who were implanted with pelvic mesh devices manufactured by companies other than Ethicon. This evidence is unreliable hearsay, has no probative value, and carries a significant risk of unfairly prejudicing Ethicon and confusing the jury. If admitted, fairness would compel that Ethicon be allowed to rebut this evidence, which would waste valuable trial time on 2 collateral matters. Accordingly, Ethicon asks that this Court preclude Plaintiff from questioning its expert witnesses or otherwise referring to unrelated lawsuits filed by those experts' patients.

As I stated earlier, "even though evidence of similar accidents may be admissible, evidence of lawsuits is generally considered inadmissible hearsay." *Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 505234, at *6 (S.D.W. Va. Feb. 5, 2014). Further, evidence of other lawsuits and the factual allegations therein is inadmissible

under Rule 403. Although other lawsuits may ultimately show that the TVT-O is defective, the jury must still find that the TVT-O caused Plaintiff's injuries. Evidence of other lawsuits is likely to confuse and mislead the jury from that task and is highly prejudicial. Therefore, I **GRANT** the Motion [ECF No. 208].

Here, however, Plaintiff argues she should be permitted to introduce evidence of mesh lawsuits brought by patients of the Ethicon's experts for other purposes – to show bias, impeach the expert, and attack the basis of their opinions. Ethicon's Motion did not address other possible nonhearsay uses and I need not rule on their admissibility now. To the extent Ethicon believes Plaintiff attempts to improperly introduce such evidence for purposes other than the truth of the matter asserted, Ethicon may object at trial.

C. ECF No. 210 – Motion to Exclude Evidence or Argument Regarding Media Reports and Documentaries

Similar to the previous Motion regarding the *New York Times* article, Plaintiff agrees that evidence of media reports and/or documentaries that are critical of pelvic mesh are also irrelevant and inadmissible. However, in accordance with my previous ruling regarding the *New York Times* article, I lack the context needed to make a substantive ruling on this matter at this time and **DENY** this Motion [ECF. No. 210] **without prejudice**.

D. ECF No. 212 – Motion to Preclude Evidence or Argument Regarding Alternative Non-Mesh Procedures

Ethicon seeks to exclude evidence of non-mesh surgical procedures as feasible alternative designs to the TVT-O device at issue in this case. In considering the

definition of a feasible alternative design under West Virginia law, I have previously explained, "I am convinced that an alternative, feasible design must be examined in the context of products—not surgeries or procedures." *Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 942 (S.D.W. Va. 2017). As I explained in *Mullins*,

> Evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT. Whether an alternative procedure could have been [performed] without the use of the TVT does nothing to inform the jury on the issue of an alternative, feasible *design* for the TVT. Instead, alternative surgeries or procedures raise issues wholly within the context of what a treating physician has recommended for patients based on the individual needs and risk factors associated with individual patients. In other words, alternative surgeries or procedures concern the medical judgment of the doctors who use TVT devices to treat stress urinary incontinence ("SUI"); other surgeries or procedures do not inform the jury on *how* the TVT's design could have feasibly been made safer to eliminate the risks that caused the plaintiffs' injuries.

Id. at 943 (citing *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999); W. Va. P.J.I. § 411).

However, Plaintiff asserts that she does not intend to introduce non-mesh surgical procedures as feasible alternative designs in support of her strict products liability claims. Therefore, I **DENY** the Motion [ECF No. 212] **AS MOOT**.

However, Plaintiff asserts that evidence of non-mesh procedures is relevant and admissible for purposes other than proving a feasible alternative design. Specifically, Plaintiff claims the evidence is relevant to her failure to warn, negligence, and punitive damages claims, as well as to rebut Ethicon's defense that the TVT-O was the "standard of care" and superior to non-mesh procedures in 2009

when Plaintiff was implanted. Ethicon's Motion did not address these other possible uses for evidence concerning non-mesh surgical procedures. To the extent Ethicon believes Plaintiff attempts to improperly introduce such evidence for purposes other than a feasible alternative design, Ethicon may object at trial.

E. ECF No. 214 – Motion to Preclude References to Online Patient Reviews of Defense Experts

Ethicon seeks to exclude any mention or introduction into evidence of online patient reviews of all defense experts. Ethicon claims that discussion of any such reviews would be irrelevant, unfairly prejudicial, and a waste of time. Ethicon does not, however, provide any specific examples of online patient reviews it wishes to exclude. Plaintiff claims that online patient reviews are highly probative evidence for cross-examination of expert witnesses in that they may speak to the experts' qualifications, their patients' experiences with mesh, their patients' outcomes, or to bias or credibility of the experts. While it is difficult to image how an online patient review could be probative of an expert's qualifications or otherwise relevant, I cannot rule on this motion without knowing what specific reviews Plaintiff may seek to introduce, the context in which each review is offered, and the arguments related to each piece of evidence. Accordingly, a ruling on this motion is premature. Because I lack the context needed to make a substantive ruling at this time, I **DENY** the Motion [ECF No. 214] **without prejudice**.

F. ECF No. 216 – Motion to Preclude Evidence or Argument that Ultrapro and TVT-Abrevvo are Feasible Alternative Designs

Ethicon seeks to preclude Plaintiff from introducing any evidence or arguing

that Ultrapro and TVT-Abbrevo, both Ethicon products, are feasible alternative designs to the TVT-O at issue in this case. Ethicon argues that evidence related to Ultrapro and TVT-Abbrevo is irrelevant, misleading, and not helpful to the jury because there is no reliable, scientific evidence that a sling created with either product would have eliminated the risk of the injuries allegedly suffered by Plaintiff, or would have been as efficient. Further, at least as to Ultrapro, Ethicon asserts that there is no evidence the product was a feasible alternative design in 2009, when Plaintiff was implanted with the TVT-O because it had (and still has) not been cleared by the FDA as a treatment for SUI. Plaintiff responds that there is scientific evidence that both Ultrapro and TVT-Abbrevo were feasible alternative designs, and were just as efficacious as the TVT-O.

I have previously held that, under West Virginia law, a strict products liability plaintiff "must prove that there was an alternative, feasible design—existing at the time of the product's manufacture—that would have eliminated the risk that injured" her. *Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952, 2016 WL 7197441, *5 (S.D.W. Va. Dec. 9, 2016). However, I have also recognized that the feasible alternative may be a "*design concept* existing at the time of the TVT's manufacture." *Mullins v. Johnson & Johnson*, 236 F.Supp.3d 90, 944 (S.D.W. Va. 2017). Thus, contrary to Ethicon's argument, the product would not have needed to receive FDA clearance as a specific SUI treatment before Plaintiff's surgery. In any event, I have clearly held that a feasible, alternative design must *eliminate* the risks that injured Plaintiff, rather than merely *reduce* them. *See Mullins v. Ethicon, Inc.*, No. 2:12-cv-02952, 2016 WL

7197441, *5 (S.D.W. Va. Dec. 9, 2016). Even Plaintiff cannot point to any evidence that either Ultrapro or TVT-Abbrevo *eliminates* the risks of the injuries she sustained. Accordingly, I **GRANT** the Motion [ECF No. 216].

G. ECF No. 218 – Supplement to Ethicon's Omnibus Motion

In this Motion, Ethicon supplements its second Motion *in Limine* contained in its Omnibus Motion [ECF NO. 71]. In its initial Motion, Ethicon moved to exclude magnified, graphic images attached to Plaintiff's case-specific expert, Dr. Margolis', supplemental report. Dr. Margolis has since served another supplemental report, dated August 5, 2019, that includes additional magnified, graphic images. Ethicon seeks to exclude these images for the same reasons as in its original Motion. For the reasons discussed in reference to ECF No. 71 above, I **DENY** this Motion [ECF No. 218].

H. ECF No. 279 – Motion to Preclude Evidence and Argument Related to Punitive Damages or Johnson & Johnson

In this Motion, Ethicon first explains that it anticipates that Plaintiff will attempt to introduce evidence relevant to her remaining punitive damages claim during her case-in-chief, including evidence related to Ethicon's state of mind and net worth. Ethicon argues that any evidence or argument solely related to punitive damages should be excluded because the court has not allowed punitive damages claims to reach the jury in related MDL cases *Lewis*, *Huskey*, and *Edwards*.

Ethicon next anticipates that Plaintiff will attempt to offer evidence related to Ethicon's parent company, Johnson & Johnson, who, according to Ethicon, Plaintiff did not name as a party in this case. Ethicon argues that any evidence relating to

Johnson & Johnson should be excluded because it is irrelevant to whether Ethicon is liable in this case.

As to Ethicon's motion to preclude evidence relating to punitive damages, I can find no functional difference between this Motion *in Limine* and a motion for summary judgment. As noted in the court's scheduling order [ECF No. 7], dispositive motions were due in this case by March 1, 2018, with any supplemental dispositive motions related to Plaintiff's ongoing medical treatment due by September 27, 2019 [ECF No. 170]. Therefore, I **DENY** this Motion [ECF No. 279] **in part** as it relates to punitive damages. Should Plaintiff fail to present evidence sufficient to support an award of punitive damages at trial, Ethicon may move for judgment as a matter of law pursuant to Federal Rule of Civil Procedure 50(a).

As to Ethicon's motion to preclude any evidence related to Johnson & Johnson, the court agrees that Johnson & Johnson is not a party to this action. In her Short Form Complaint filed with the court [ECF No. 1], Plaintiff only identified Ethicon, Inc. as a defendant in response to question six. She did not identify Johnson & Johnson as a defendant. Indeed, this court has never recognized the existence of more than one defendant in this case. The docket and case caption both only reflect one defendant – Ethicon, Inc. Further, Rule 10(a) of the Federal Rules of Civil Procedure requires a complaint to name all the parties.

Plaintiff argues Johnson & Johnson should be considered a defendant because an earlier version of the Short Form Complaint she emailed to Ethicon's counsel, but did not file with this court, did check both Ethicon and Johnson & Johnson as

defendants. While, pursuant to Pretrial Order #49, that earlier version may have been sufficient for purposes of tolling the statute of limitations against Johnson & Johnson, it was ineffective for purposes of establishing Johnson & Johnson as a party in this case. Because the operative Complaint [ECF No. 1] does not name Johnson & Johnson as a party, any evidence related to Johnson & Johnson for purposes of liability and/or damages is irrelevant. Accordingly, I **GRANT** the Motion [ECF No. 279] **in part.**

I. ECF No. 320 – Second Supplement to Defendant's Omnibus Motion

In this Motion, Ethicon again supplements its second Motion *in Limine* contained in its Omnibus Motion [ECF NO. 71] to exclude graphic images of Plaintiff's vulvar abscess. Now, in addition to the images attached to Dr. Margolis' expert reports, Ethicon also seeks to exclude similar images in Plaintiff's July 8, 2020 medical records, Bates numbers SUTPHINA_PSR_01990-1991. For the reasons discussed in reference to ECF No. 71 above, I also **DENY** this Motion [ECF No. 320].

III. Conclusion

For the reasons stated above, ECF Nos. 48, 208, and 216 are **GRANTED**; ECF Nos. 128, 130, 210, 212, 214, 218, 224, 227, 263, 264, 265, and 320 are **DENIED**; and ECF Nos. 71 and 279 are **GRANTED in part** and **DENIED in part.**

ENTER: August 27, 2020

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE